K122526

510(K) Summary

NOV 16 2012

Date Prepared: October 12, 2012

510(k) Submitter	Contact for Official Correspondence
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General Information			
Trade Name	360° Gas Assisted Endoscopic Applicator	Common Name	Endoscopic Applicator
Classification Information	Endoscope and accessories per 21 CFR 876.1500 (Class II)	Product Code	GCJ
		Panel	General & Plastic Surgery
Predicate Devices	Air Assisted Endoscopic Applicator, K042834 cleared on February 11, 2005		

Device Description

The 360° Gas Assisted Endoscopic Applicator is a sterile, single-use, disposable device intended for the application of two non-homogeneous liquids. The 360° Gas Assisted Endoscopic Applicator is designed with two luer connectors at the proximal end, which is used for connection to two syringes containing the non-homogeneous liquids. There is also a connector at the proximal end to be attached to a tubing set which is connected to a compressed air/inert gas power source. The 360° Gas Assisted Endoscopic Applicator is packaged with an air line with filter in a PETG tray/Tyvek lid configuration and sterilized using ethylene oxide. Five individually sterile packaged applicators are contained in a shelf carton along with the instructions for use.

Intended Use / Indications

The 360° Gas Assisted Endoscopic Applicator is intended for the application of two non-homogenous fluids.

Substantial Equivalence Comparison

The endoscopic applicator subject to this special 510(k) incorporates a flexible Pebax tube at the distal end of the applicator which allows for directional positioning of the tip.

Summary of Non-Clinical Performance Data

The 360° Gas Assisted Endoscopic Applicator was evaluated through design verification and biocompatibility testing. Biocompatibility testing performed in accordance with ISO 10993 – *Biological evaluation of medical devices, Part 1 – Evaluation and tests (2009)* show the device is considered safe for use for its intended biocontact. Non-clinical testing included the tests listed below and showed the test articles met the pre-defined acceptance criteria, therefore demonstrating the mechanical integrity and suitability of the device for its intended use over the labeled shelf life.

- Pull (Torque) Testing
- Leak Testing
- Spray Testing
- Mixing Test
- Sterilization Validation
- Shelf life Evaluation

Substantial Equivalence Conclusion

The 360° Gas Assisted Endoscopic Applicator does not raise new questions of safety or effectiveness when compared to the predicate devices and is, therefore, substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 16, 2012

Micromedics, Incorporated
% Ms. Jodi Raus MBA, RAC
Director of Regulatory, Clinical and Quality Affairs
1270 Eagan Industrial Road, Suite 120
Saint Paul, Minnesota 55121

Re: K122526
Trade/Device Name: 360° Gas Assisted Endoscopic Applicator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 17, 2012
Received: October 18, 2012

Dear Ms. Raus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number: K122526

Device Name 360° Gas Assisted Endoscopic Applicator

Indications for Use The 360° Gas Assisted Endoscopic Applicator is intended for the application of two non-homogenous fluids.

Prescription Use ___X___ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K122526